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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,434	07/24/2003	Andrew Joseph Friedman	PRD-0007-US-CIP	9625

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,434	FRIEDMAN ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/18/2007 has been entered.

Claim(s) 6-8 have been cancelled. Claim(s) 1-5 are pending. Claim(s) 1 has been amended. Claim(s) 1-5 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The double patenting and 103(a) rejection of the last Office Action are maintained for reasons of record and are either repeated below for Applicant's convenience or modified below as a result of the new claim amendments.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/385,597. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims disclose an obvious variation of a method of contraception by administering to a menstruating female a composition comprising estrogen and progestogen for 42 consecutive days followed by a hormone-free period.

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/955,276. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims disclose an obvious variation of a method of contraception by administering to a menstruating female a composition comprising ethinyl estradiol and norgestimate for 42 consecutive days followed by a hormone-free period. In both cases, the subtle differences in dosages and length of administration are obvious to one of ordinary skill in the art to optimize.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's request to address these grounds of rejection until allowable subject matter is disclosed is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being obvious over Kovacs et al. (The British Journal of Family Planning, 1994, 19, pg. 274-275) in view of Smallwood et al. ("Efficacy and Safety of a Transdermal Contraceptive System" Obstetrics & Gynecology, vol. 98, no. 5, part 1, 2001, pg. 799-805).

The instant claims are directed to a method of contraception comprising administering to a menstruating female a transdermal composition comprising ethinyl estradiol and norelgestromin for at least 56 successive days.

Kovacs et al. teach a trimonthly method of contraception (pg. 274, left column, paragraph 1) for menstruating women (pg. 275, right column, paragraph 9). The contraceptive comprises a daily dosage of ethinyl estradiol (estrogen) and a progestogen (levonorgestrel) (pg. 274, right column, paragraph 3) for 12 weeks followed

by one week of placebo (pg. 274, left column, paragraph 1). Half of the female patients discontinued the regimen because of breakthrough bleeding (pg. 274, left column, paragraph 1).

However, Kovacs et al. does not specifically disclose the combination of ethinyl estradiol and norelgestromin.

Smallwood et al. teach a method of contraception comprising administering a daily transdermal composition comprising ethinyl estradiol (20 μg) and norelgestromin (150 μg) for 21 consecutive days followed by 1-week hormone-free period. This method provides enhanced bleeding control and is well tolerated (abstract). The women must be sexually active and at risk of pregnancy as well as have regular menstrual cycles (pg. 800, right column, second paragraph).

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to substitute the contraceptive composition in the regimen as taught by Kovacs et al. with the composition comprising ethinyl estradiol and norelgestromin as taught by Smallwood et al.

A person of ordinary skill in the art would have been motivated to make this substitution because: (1) both Kovacs and Smallwood et al. teach a method of contraception by the administration of hormones; (2) both Kovacs and Smallwood et al. disclose the use of hormones, specifically ethinyl estrodiol (estrogen) in their regimen; and (3) because of the enhanced bleeding control and good tolerance in females in the regimen disclosed by Smallwood et al. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in providing a method of contraception in

females by administering a transdermal composition comprising ethinyl estradiol and norelgestromin for at least 56 successive days.

Response to Arguments

Applicant argues that cited references do not teach a transdermal extended contraceptive regimen. This is not persuasive because clearly Kovacs et al. teach a trimonthly method of contraception for 12 weeks and Smallwood et al. teach a method of contraception for 21 consecutive days using a transdermal composition.

Applicant argues that the cited references do not teach that extended transdermal contraceptive regimens provide enhanced continuation and satisfaction rates, longer median time-to-first bleed, fewer mean bleeding days through day 56, and reduced median incidence of headaches. Applicant also argues that these limitations are unexpected and surprising when compared to cyclic transdermal administration.

This is not persuasive because these limitations will be given little patentable weight. Firstly, the claims are drawn to a method of contraception and not to enhanced continuation and satisfaction rates, longer median time-to-first bleed, fewer mean bleeding days through day 56, and reduced median incidence of headaches. Secondly, these limitations are an inherent property or result when the same active agent is administered to the same patient population in the same dosage.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical

chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Furthermore, these limitations are not considered unexpected or surprising because Smallwood et al. teach that the disclosed method of contraception provides enhanced bleeding control and is well tolerated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC